



JC10 Rec'd PCT/PTO 09 NOV 2005

PCT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: ) Art Unit:  
FENGER, Mogens )  
Serial No.: 10/527,806 ) Examiner:  
Filed: March 14, 2005 ) Washington, D.C.  
For: METHOD OF RAPID DETECTION ) November 9, 2005  
OF MUTATIONS AND NUCLEO- ) Docket No.: FENGER=2  
TIDE POLYMORPHISMS... ) Confirmation No.:

INFORMATION DISCLOSURE STATEMENT [IDS]

U.S. Patent and Trademark Office  
Customer Service Window  
Randolph Building  
401 Dulany Street  
Alexandria, VA 22314

Sir :

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed:

[ ] A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application. See 37 CFR 1.97(b)(1) and (3).

[X] B. before the mailing date of a first office action on the merits. See 37 CFR 1.97(b).

[ ] C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary certification (box "i" below) or paid the necessary fee (box "ii" below). See 37 CFR 1.97(c)(2).

[ ] i. Counsel certifies that, upon information and

belief, each item of information listed herein was either (a) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS or (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

[ ] ii. Credit Card Payment Form, PTO-2038, authorizing payment for the fee set forth in 1.17(p), presently believed to be \$180, is attached.

[ ] D. after (A), (B) and (C) above, but before payment of the issue fee. Applicant petitions under 37 C.F.R. 1.97(d) for consideration of this IDS. A Credit Card Payment Form, PTO-2038, authorizing payment for the fee set forth in 1.17(p)(1), presently believed to be \$180 is attached. Counsel certifies that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

[ ] E. As a submission in accordance with the transitional procedure for limited examination after final rejection pursuant to 37 CFR §1.129(a). Pursuant to MPEP §706.07(g), page 700-66, col. 2 (August 2001), this IDS is treated as if filed with a period set forth in 37 CFR §1.97(b) and considered without the petition and petition fee required by 1.97(d).

[ ] F. As a submission with or after a request for continued examination under CFR §1.114, and before the mailing of a first office action on the RCE. See 37 CFR §1.97(b)(4).

2. In accordance with 37 C.F.R. 1.98, this IDS includes a

list (e.g., form PTO-1449) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document is attached, except as explained below.

[ ] While an IDS filed under §1.97 must contain a "list of all patents, publications or other information submitted for consideration by the Office", see §1.98(a) (1), the only requirement for the list is that it provide the information set forth in §1.98(b). There is no requirement that a form PTO-1449 be used (MPEP §609 merely says that use of this form is "encouraged"). Counsel has used a list provided to him by Applicants, and not transferred the information to a PTO-1449, to avoid the risk of any inadvertent error in transferring the information.

[X] A. Documents AA-AZ are U.S. Patents or U.S. Patent Publications, and hence copies of these documents have not been provided. See 37 CFR 1.98(a)(2)(ii).

[ ] B. Documents \_\_\_\_\_ are deemed substantially cumulative to documents \_\_\_\_\_, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.

[ ] C. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120:

[insert serial number/filing date]

Applicants identify these documents by attaching hereto copies of the form PTO-892s and PTO-1449s from the files of the prior applications or a fresh PTO-1449 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application. If copies of any of these documents cannot be found in the files of the prior applications, the Examiner is requested to so notify counsel before taking action in this case, so replacement copies can be submitted. While an IDS filed under §1.97 must contain a "list of all patents, publications or other information submitted for

consideration by the Office", see §1.98(a) (1), the only requirement for the list is that it provide the information set forth in §1.98(b). There is no requirement that a form PTO-1449 be used (MPEP §609 merely says that use of this form is "encouraged") and no prohibition on submitting a copy of a form PTO-1449 or form PTO-892 from a prior case. Indeed, the re-use of such forms is desirable as it avoids error in transferring the information, and evidences that the reference was considered in a prior application. A previously accepted PTO-1449, or an examiner-prepared PTO-892, necessarily complies with §1.98(b).

[ ] 3. Documents \_\_\_\_\_ are not in the English language. In accordance with 1.98(a)(3), Applicants state:

- [ ] documents \_\_\_\_\_ already contain an English language abstract, summary or claim set.
- [ ] a publicly available abstract is attached to each of documents \_\_\_, and the source of each abstract is indicated thereon.
- [ ] documents \_\_ are patents or published patent applications for which counterpart English language patents or patent applications exist, and are enclosed, as follows:

<u>Foreign Lang. Doc.#</u>	<u>English Lang. Doc.#</u>
[insert]	[insert]

- [ ] applicants have prepared an English translation of at least the pertinent portions of documents \_\_\_\_\_, and copies are attached.
- [ ] A concise explanation of the relevance of documents \_\_\_\_\_ is found in the attached search report from the \_\_\_\_\_ Patent Office (see reply to Comment 68 in the preamble to the final rules; 1135 OG 13 at 20).
- [ ] A concise explanation of the relevance of documents \_\_\_\_\_ appears in the present specification.
- [ ] A concise explanation of the relevance of documents \_\_\_\_\_ is set forth as follows:  
[Insert concise explanation of relevance]

4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).

5. If the month of publication of a nonpatent reference is not stated, it is because it is not apparent from review of the reference. If requested to do so by the Examiner, Applicants will attempt to locate and write to the publisher.

If the publication date of a cited document is set forth only as a publication year, and that year is prior to the year of filing or, if priority is claimed, year of priority of this application, then the particular month of publication is not in issue. Likewise if that publication year is after the year of filing of this application, the month of publication is not in issue.

If the date of publication of a nonpatent reference is stated, then, except as explained below, it is the nominal date stated in the reference, or in a larger document (journal or book) from which the reference was extracted. Applicants reserve the right to challenge this date by contacting the publisher to determine the actual shipment date, or by contacting recipients to determine the receipt dates.

6. Other information being provided for the examiner's consideration follows:

[insert other information]

7. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

8. The Commissioner is hereby authorized and requested to charge any additional fees which may be required in connection

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with this paper or credit any overpayment to Deposit Account No.  
02-4035.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.  
Attorneys for Applicant

By:

  
Iver P. Cooper  
Reg. No. 28,005

624 Ninth Street, N.W.  
Washington, D.C. 20001  
Telephone: (202) 628-5197  
Facsimile: (202) 737-3528  
IPC:lms  
G:\ipc\g-i\hoib\FINGER2\ptoids.wpd



FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT  
LIST OF DOCUMENTS CITED BY APPLICANT  
(Use several sheets if necessary)

ATTY DOCKET NO: FENGER=2

SERIAL NO: 10/527,806

APPLICANT: FENGER, Mogens

FILING DATE: March 14, 2005

GROUP:

## U.S. PATENT DOCUMENTS (include at least patentee, patent number and issue date)

EXAMINER INITIAL		DOCUMENT NUMBER								DATE	PATENTEE	CLASS	SUB-CLASS	FILING DATE IF APPROP.
	AA	6	1	8	0	3	4	0		Jan. 30, 2001	Nelson			
	AB	5	2	4	2	6	0	2		Sep. 7, 1993	Richardson et al			
	AC	5	3	6	0	9	7	2		Nov. 1, 1994	DiFoggio et al			
	AD	5	9	5	5	7	3	7		Sep. 21, 1999	Halliday et al			
	AE	5	5	2	8	3	6	8		June 18, 1996	Lewis et al			
	AF	5	8	6	1	2	5	6		Jan. 19, 1999	Glass et al			
	AG	5	7	2	3	2	9	4		March 3, 1998	Glass et al			
	AH	5	3	4	8	0	0	2		Sep. 20, 1994	Caro			
	AI	5	2	8	3	1	7	4		Feb. 1, 1994	Arnold, Jr, et al			
	AJ	5	7	5	6	0	1	1		May 26, 1998	Woodhead et al			
	AK	5	8	4	0	8	7	3		Nov. 24, 1998	Nelson et al			
	AL	6	1	8	0	3	4	0		Jan. 30, 2001	Nelson			
	AM	5	8	7	9	8	8	5		March 9, 1999	Becker			
	AN	5	7	6	5	7	0	9		May 26, 1998	Nelson et al			
	AO	5	6	5	8	7	3	7		Aug. 19, 1997	Nelson et al			
	AP	5	8	2	7	6	5	6		Oct. 27, 1998	Nelson et al			
	AQ	5	6	4	2	2	9	2		June 24, 1997	Itai et al			
	AR	6	0	2	2	6	8	6		Feb. 8, 2000	Garman et al			
	AS	6	0	4	8	6	9	0		Apr. 11, 2000	Heller et al			
	AT	5	6	3	3	1	3	4		May 27, 1997	Shuber			
	AU	6	5	8	4	4	1	3		June 24, 2003	Keenan et al			
	AV	6	2	6	1	7	8	2		July 17, 2001	Lizardi et al			
	AW	6	3	4	1	2	5	7		Jan. 22, 2002	Haaland			
	AX	5	8	4	9	4	8	6		Dec. 15, 1998	Heller et al			
	AY	6	6	7	5	1	0	6		Jan. 6, 2004	Keenan et al			
	AZ	5	6	3	5	3	5	2		June 3, 1997	Urdea et al			
EXAMINER											DATE CONSIDERED			

EXAMINER: Initial if reference considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



SHEET 2 OF 3

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE  INFORMATION DISCLOSURE STATEMENT LIST OF DOCUMENTS CITED BY APPLICANT (Use several sheets if necessary)									ATTY DOCKET NO: FENGER=2	SERIAL NO: 10/527,806							
									APPLICANT: FENGER, Mogens								
									FILING DATE: March 14, 2005							GROUP:	
FOREIGN PATENT DOCUMENTS (Include at least document number, publication date and country)																	
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION YES/NO				
	BA	0	6	1	4	0	7	9	07SEP1994	EP			N/A				
OTHER DOCUMENTS (Include author, title, name of publication, volume, pages & date of publication)																	
	BB	Varmuza, Kurt, <u>Chemometrics: Statistics and multivariate data analysis in chemistry – Application Examples</u> , Int. Conf. On Statistics and Related Fields, 5-9 June 2003, pages 1-29, XP002267859, Honolulu, Hawaii 2003, page 5															
	BC	Lee, K R, et al, <u>Chemometrics approach to the determination of polymorphism of a drug compound by infrared spectroscopy</u> , Drug Development and Industrial Pharmacy, USA Feb. 2000, vol. 26, no. 2, Feb. 2000, pages 135-147, XP002267858, figures 1-17															
	BD	<u>Fellenberg et al, Correspondence analysis applied to microarray data</u> , PNAS, September 11, 2001, vol 98, no. 19, 10781-10786.															
	BE	<u>Crescenzi, The main biological determinants of tumor line taxonomy elucidated by a principal component analysis of microarray data</u> , FEBS Letters, 2001, Vol. 507, p. 114-118															
	BF	<u>Maurer et al, Differential Gene Expression Profile of Glucocorticoids, Testosterone, and Dehydroepiandrosterone in Human Cells</u> , Horm. Metab. Res. 2001, Vol. 33, p. 691-695															
	BG	<u>Fung, et al, Proteinchip Clinical Proteomics: Computational Challenges and Solutions</u> , Computational Proteomics Suppl. March 2002, Vol. 32, pp. 34-38 & 40-41.															
	BH	<u>F. Sanger et al, Nucleotide sequence of bacteriophage Φ X174 DNA</u> , Nature, Vol. 265, Feb. 24, 1977, pp. 687-695.															
	BI	<u>Van Gemen et al, The one-tube quantitative HIV-1 RNA NASBA: Precision, accuracy and application</u> , Cold Spring Harbor Laboratory, 4:S177-S184, 1995															
	BJ	<u>Liu et al, Restriction Endonuclease Fingerprinting (REF): A sensitive method for screening mutations in long, contiguous segments of DNA</u> , BioTechniques, Vol. 18, No. 3 (1995), pp. 470-477.															
	BK	<u>Abramson et al, Nucleic acid amplification technologies</u> , Current Opinion in Biotechnology 1993, 4:41-47															
	BL	<u>Schweitzer et al, Combining nucleic acid amplification and detection</u> , Current Opinion in Biotechnology 2001, 12:21-27															
	BM	<u>Ørum et al, Detection of the Factor V Leiden Mutation by Direct Allele-specific Hybridization of PCR Amplicons to Photoimmobilized Locked Nucleic Acids</u> , Clinical Chemistry 45:11 1898-1905 (1999)															
	BN	<u>Nielsen et al, Sequence-Selective Recognition of DNA by Strand Displacement with a Thymine-Substituted Polymide</u> , Science, Vol 254, pp. 1497-1500, December 6, 1991.															
	BO	<u>Wayne M. Barnes, PCR amplification of up to 35-kb DNA with high fidelity and high yield from λ bacteriophage templates</u> , Proc. Natl. Acad. Sci. USA, Vol 91, pp. 2216-2220, March 1994, Genetics															
	BP	<u>Sjöroos et al, Solid-Phase PCR with Hybridization and time-resolved Fluorometry for Detection of HLA-B27</u> , Clinical Chemistry 47:3, 498-504 (2001)															
	BQ	<u>Oroskar et al, Detection of immobilized amplicons by ELISA-like techniques</u> , Clinical Chemistry 42:9, 1547-1555 (1996)															
	BR	<u>Steel et al, Immobilization of nucleic acids at solid surfaces: effect of oligonucleotide length on layer assembly</u> , Biophysical Journal, Vol. 79, August 2000, 975-981															
	BS	<u>Hovig et al, Constant denaturant gel electrophoresis, a modification of denaturing gradient gel electrophoresis, in mutation detection</u> , Mutation Research, 262 (1991) Elsevier, pp. 63-71															
EXAMINER										DATE CONSIDERED							
EXAMINER: Initial if reference considered. Draw line through citation if not in conformance and not considered. Include copy of this form With next communication to applicant.																	



SHEET 3 OF 3

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY DOCKET NO: FENGER=2	SERIAL NO: 10/527,806
INFORMATION DISCLOSURE STATEMENT LIST OF DOCUMENTS CITED BY APPLICANT (Use several sheets if necessary)			
		APPLICANT: FENGER, Mogens	
		FILING DATE: March 14, 2005	GROUP:
	BT	Sarkar et al, Dideoxy Fingerprinting (ddF): A Rapid and Efficient Screen for the presence of mutations, Genomics 13, 441-443 (January 21, 1992).	
	BU	Fischer et al, DNA fragments differing by single base-pair substitutions are separated in denaturing gradient gels: Correspondence with melting theory, Proc.Natl. Acad. Sci, USA, Vol. 80, pp. 1579-1583, March 1983, Biochemistry	
	BV	Orita et al, Rapid and sensitive detection of point mutations and DNA polymorphisms using the polymerase chain reaction, Genomics 5, 874-879 (1989)	
	BW	Maxam et al, A new method for sequencing DNA, Proc. Natl. Acad. Sci, USA, vol. 74, No. 2, pp. 560-564, Feb. 1977	
	BX	Matthews et al, Analytical strategies for the use of DNA probes, Analytical BioChemistry 169, 1-25 (1988)	
EXAMINER		DATE CONSIDERED	
EXAMINER: Initial if reference considered. Draw line through citation if not in conformance <u>and</u> not considered. Include copy of this form with next communication to applicant.			